NOV 2 0 2003

K033593

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CLEAR MEDICAL, INC.

1776-136th Place NE
Bellevue, WA 98005-2328
Tel: (425) 401.1414
Fax: (425) 401.1515

510(k) SUMMARY

Reference: Clear Medical, Incorporated
Section 510(k) Notification
Reprocessed Single Use, Electric and Mechanical Biopsy Forceps

Classification name:	Instrument, Biopsy, Mechanical, Gastrointestinal
Common/Usual Name:	Gastrointestinal Biopsy Forceps
Proprietary Name:	Reprocessed Biopsy Forceps
Establishment Reg. No.:	3017110
Classification:	The FDA has classified gastrointestinal biopsy forceps as a Class II device in 21 CFR 876.1075.

Clear Medical intends to market Reprocessed Used Disposable Biopsy Forceps. Reprocessing Biopsy Forceps is performed by Clear Medical to Clear Medical protocol Number 40003.

"Reprocessed," means all operations performed to render a contaminated single-use device patient ready (*Enforcement Priorities for Single-Use Devices Reprocessed by Third Party Reprocessors and Hospitals*). Clear Medical is a "third party reprocessor" and reprocesses used, single-use medical devices.

Clear Medical believes that Used Disposable Biopsy Forceps can be considered "reusable - by Clear Medical" as defined in the Food and Drug Administration Compliance Policy Guide #7124.16: they are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

Clear Medical, Inc. reprocessed Microvasive, single use, electric and mechanical biopsy forceps are intended to be used during GI procedures for endoscopic tissue sample acquisition.

Clear Medical Reprocessed Used Disposable Biopsy Forceps are substantially equivalent to disposable biopsy forceps currently marketed new by Microvasive under 510(k) 932266.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Mr. Mike Kovacs
Clear Medical, Inc.
1776-136th Place NE
Bellevue, WA 98005-2328

Re: K033593
Trade/Device Name: SEE ENCLOSURE 1
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KGE
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instruments
Regulatory Class: I
Product Code: 78 FCL
Dated: November 7, 2003
Received: November 13, 2003

Dear Mr. Kovacs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

2 Enclosures

ENCLOSURE 1 K033593

CLASS I: FCF 21CFR §876.1075

Adven Medical, Inc Reprocessed Mechanical and Electric Single Use Biopsy Forceps
Manufacturer: MICROVASIVE

Radial Jaw* 3 Max Capacity Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1586	3.3	160	3.8	Yellow
1587 with needle	3.3	160	3.8	Yellow
1588	3.3	240	3.3	Orange
1589 with needle	3.3	240	3.8	Orange

Radial Jaw* II Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1562	2.2	160	2.8	Yellow
1563 with needle	2.2	160	2.8	Yellow
1564	2.2	240	2.8	Orange
1565 with needle	2.2	240	2.8	Orange

Radial Jaw* LC II Large Capacity Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1591	2.2	160	2.8	Yellow
1592 with needle	2.2	160	2.8	Yellow
1593	2.2	240	2.8	Orange
1594 with needle	2.2	240	2.8	Orange

Radial Jaw Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1260	2.2	160	2.8	Yellow
1263 with needle	2.2	160	2.8	Yellow
1271	2.2	240	2.8	Orange
1265 with needle	2.2	240	2.8	Orange

Radial Jaw MC 3.3 Single-Use Max Capacity Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1260	2.2	160	2.8	Yellow
1263 with needle	2.2	160	2.8	Yellow
1271	2.2	240	2.8	Orange
1265 with needle	2.2	240	2.8	Orange
1582	3.3	160	3.8	Yellow
1583 with needle	3.3	160	3.8	Yellow
I 584	3.3	240	3.8	Orange
1585 with needle	3.3	240	3.8	Orange

Radial Jaw LC Large Capacity Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1273	2.2	240	2.8	Orange
1274 with needle	2.2	240	2.8	Orange

Radial Jaw GP Gastro-pediatric Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1281	1.8	160	2.0	Yellow
1286 with needle	1.8	160	2.0	Yellow

Multibite™ Multiple Sample Single-Use Biopsy Forceps

Manufacturer Numbers	Length (cm)	Working Channel (mm)
1010	160	2.8
1012	240	2.8

Radial Jaw 3™ Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1534 (Box 5)	2.2	160	2.8	Yellow
1535 with needle (Box 5)	2.2	160	2.8	Yellow
1536 (Box 5)	2.2	240	2.8	Orange
1537 with needle (Box 5)	2.2	240	2.8	Orange

Radial Jaw 3 Large Capacity Single-Use Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)	Working Channel (mm)	Color Code
1281	1.8	160	2.0	Yellow
1286 with needle	1.8	160	2.0	Yellow
1596	2.2	160	2.8	Yellow
1597 with needle	2.2	160	2.8	Yellow
1598	2.2	240	2.8	Orange
1599 with needle	2.2	240	2.8	Orange

CLASS II; KGE; 21CFR §876.4300

Radial Jaw™ 3 Single-Use Hot Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)
1550 (Box 5) (Olympus® Connector)	2.2	240
1551 (Box 5) (Microvasive® Connector)	2.2	2.40

Radial Jaw Hot Biopsy Forceps

Manufacturer Numbers	Jaw O.D. (mm)	Length (cm)
1274 (Box 5) (Microvasive® Connector)	2.2	240
1277 (Box 5) (Olympus® Connector)	2.2	2.40

1266	1.8	100	2.0	Blue
1267	2.2	100	2.8	Blue
1268 with needle	2.2	100	2.8	Blue
1269 with needle	1.8	100	2.0	Blue

1530 (Box 5)	2.2	100	2.8	Blue
1531 with needle (Box 5)	2.2	100	2.8	Blue
1266	1.8	100	2.0	Blue
1267	2.2	100	2.8	Blue
1268 with needle	2.2	100	2.8	Blue
1269 with needle	1.8	100	2.0	Blue

XX 1260-20 Radial Jaw 20-pack 2.2 160 2.8 Yellow

XX 1263-20 Radial Jaw 20-pack with needle 2.2 160 2.8 Yellow

XX 1265-20 Radial Jaw 20-pack with needle 2.2 240 2.8 Orange

XX1267-20 Radial Jaw 20-pack 2.2 240 2.8 Orange

510)k) Number: K033593

Device Name: Reprocessed Used Disposable Biopsy Forceps

CMI intends to reprocess used disposable hot and cold biopsy forceps manufactured by Micovasive.

Cold biopsy forceps are intended to be used through an endoscope to remove polyps and/or tissue specimens throughout the alimentary tract

Hot Biopsy Forceps are intended to be used through an endoscope to cauterize and remove polyps and/or tissue specimens throughout the alimentary tract.

CMI reprocessed biopsy forceps are disposable unless reprocessed again by Clear Medical, Inc.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033593